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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,589	02/27/2004	Sang Van	NDTCO.030A	7772
20995 7590 02/06/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER GUDIBANDE, SATYANARAYAN R	
			ART UNIT 1654	PAPER NUMBER
			NOTIFICATION DATE 02/06/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	Application No. 10/789,589	Applicant(s) VAN ET AL.	
	Examiner Satyanarayana R. Gudibande	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,7,9-17 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,12-17 and 21-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 7 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of group II and election of structure I and SEQ ID NO: 8 as species in the reply filed on 9/10/07 was acknowledged and the traversal arguments were answered in the office action dated 10/3/07.

Applicant's amendment to claims and remarks in the response filed on 11/15/07 has been acknowledged.

Claims 1, 3, 7, 9-17 and 21-27 are pending.

Claims 9, 10, 12-17 and 21-27 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 2, 4-6, 8 and 18-20 have been canceled.

Claims 1, 3, 7 and 11 are examined on the merit.

Any objections and rejections made in the office action dated 10/3/07 and not specifically mentioned here are considered withdrawn.

Prior art search indicated that the formulae I-IV and the peptide species with SEQ ID NO: 8 have been found to be free of art.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 101***

Applicant's arguments, see page 8, filed 11/15/07, with respect to rejection of claim 1 have been fully considered and are persuasive. The rejection of claim 1 under 35 USC § 101 has been withdrawn.

***Claim Rejections - 35 USC § 102(b)***

Applicant's arguments, see page 10, filed 11/15/07, with respect to rejection of claim 1 have been fully considered and are persuasive. The rejection of claim 1-3 under 35 USC § 102(b) has been withdrawn.

***Claim Rejections - 35 USC § 112***

Applicant's arguments, see page 8-10, filed 11/15/07, with respect to rejection of claim 1 have been fully considered and are persuasive. The rejection of claim 1, 3, 7 and 11 under 35 USC § 112 First paragraph under written description has been withdrawn.

***Double Patenting***

Applicant's arguments, see page 10, filed 11/15/07, with respect to rejection of claim 1 have been fully considered and are persuasive. The rejection of claim 1 and 3 under obvious type double patenting has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendments to claims as shown below.

*New grounds of Rejections*

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite “[A] composition for delivering an isolated DNA to a cell, comprising: a biodegradable polyacetal-peptide, wherein the biodegradable polyacetal-peptide comprises at least one recurring unit represented by a formula selected from the group consisting of (I) and (II)”.

*Lack of Ipsis Verbis Support*

The specification lacks any Ipsis Verbis support that would support for “[A] composition for delivering an isolated DNA to a cell, comprising: a biodegradable polyacetal-peptide, wherein the biodegradable polyacetal-peptide comprises at least one recurring unit represented by a formula selected from the group consisting of (I) and (II)”. The specification discussing support for the claim amendment in paragraphs [0007] to [0011] and [0029] to [0030] require complex that is comprised of (a) a polynucleotide and (b) a polyacetal-polypeptide. The claim as

instantly recited does not require the two constituents (a) and (b) as required by the claims as originally recited. Therefore, the instantly recited claims lack literal support in the specification.

### **Lack of Implicit Support**

It is acknowledged that there is it should be noted, that exact terms need not be used *in haec verba* to satisfy the written description requirement of the first paragraph of 35 U.S.C. 112. The instantly amended claims recite a composition '**for delivering an isolated DNA**' wherein the composition comprises of a biodegradable polyacetal-polypeptide. The claim as amended does not require a complex of (a) DNA and (b) polyacetal-polypeptide complex. The instant composition requires only the polyacetal-polypeptide in the composition and as recited has an intended use for transfecting DNA at a later stage. Thus the instantly claimed invention alters the scope of the invention. The instantly claimed invention also lacks implicit support from the specification as originally filed. The originally disclosed specification clearly states that 'the invention is drawn to complex for delivering a polynucleotide' [0007], 'a method of making the complex for delivering a polynucleotide to a cell which includes the steps of intermixing the polyacetal-peptide and the polynucleotide' [0011] and 'Preferred embodiments are directed to biodegradable polymer-peptides, compositions which include a complex of one or more polynucleotides along with a biodegradable polymer-polypeptide, methods of making the polynucleotide/polymer-polypeptide complexes, and methods of using the complexes in cell transfection. Preferred embodiments are directed to biodegradable polyacetal-peptides' [0030], all require a complex of polynucleotide and polyacetal-polypeptide (a two component system).

However, the instantly amended claims are drawn to a composition that requires only the polyacetal-polypeptide (one component system). Therefore, the instantly amended claims lacks implicit support from the specification as originally disclosed.

In conclusion, the specification does not provide reasonable support to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as amended.

Applicant's amendment to claims 1, 3 and 7 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

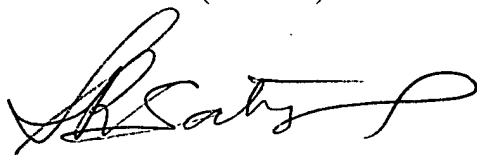
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Satyanarayana R. Gudibande, Ph.D.  
Art Unit 1654

  
1/31/8  
**ANISH GUPTA**  
**PRIMARY EXAMINER**